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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,047

08/29/2006

Dagfinn Lovhaug

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GE HEALTHCARE, INC.

IP DEPARTMENT 101 CARNEGIE CENTER

PRINCETON, NJ 08540-6231

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,047	3LOVHAUG, DAGFINN	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/29/06</u> | 6) <input type="checkbox"/> Other: _____ |

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/29/06 wherein the specification and claims 1-4, 6, and 9 were amended.

Note: Claims 1-11 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to pharmaceutical as set forth in independent claim 1. In addition, Applicant has a claim directed to a kit comprising a peptide-chelate conjugate and a reducing agent.

112 FIRST PARAGRAPH REJECTIONS

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity

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that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to: (1) what specific Z group Applicant is referring to that Applicant is claiming that is compatible to the instant invention; (2) what particular biomodifier group(s) may be attached to any positions of V and L that are compatible with the instant invention; and (3) what specific moiety that emit or cause to emit detectable radiation; what moiety which affects local electromagnetic fields; what moieties which absorb or scatter radiation energy; what heavy metals and compounds thereof, and what moieties which generate a detectable substance is/are compatible with the instant invention. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe

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an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 SECOND PARAGRAPH REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and 6-10 1, line 9: The phrase 'aryl containing substituent' is confusing in claim 1, line 9. Did Applicant intend to write 'a substituted aryl substituents'? Since claims 2, 3, and 6-10 depend on independent claim 1, those claims are also vague and indefinite.

Claim 1, lines 10-11: A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

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raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 (lines 10-11) recites the broad recitation 'a Arg mimetics', and the claim also recites 'Phe[4-guanidino] or Gly-4-piperidyl[N-amidino] which is the narrower statement of the range/limitation.

Claims 1 (lines 12 and 14), 2 (lines 6-7, and 8-9), 9 (lines 11-12 and 13-14):

The claims as written are ambiguous because in each occurrence a single amino acid appears beside 'SEQ ID No.1'. Specifically, the claims are confusing because SEQ ID No. 1 is the sequence containing 'Val-Tyr-Ile-His-Pro; thus, it is unclear how the claims should be interpreted when SEQ ID No. 1 is adjacent to a single amino acid. Please clarify so that one can ascertain what is being claimed.

Claims 1-10: The claims as written are ambiguous because of the phrase 'the residues Val and Ile at position 3 and 5 may optionally be replaced with amino acids capable of forming a bridging unity wherein the bridge contain...unit' (see claim 1, lines 16-18). In particular, the phrase is ambiguous because it is unclear what specific amino acids Applicant is replacing Val and Ile with that will yield the desired results. since claims 2-10 depend on independent claim 1, those claims are also vague and indefinite.

Claims 1-10: The claims as written are ambiguous. In particular, in independent claim 1, lines 20-21, the phrase 'M where present denotes and imagable

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moiety...procedure'. In particular, it is unclear what specific moieties Applicant is claiming that are compatible with the instant invention or if Applicant is state that all imaginable moieties are being claim since a particular moiety may not be compatible with SEQ ID No. 1. Since claim 2-10 depend from independent claim 1, those claims are also vague and indefinite.

Claim 3, line 2: The claim as written are ambiguous because of the phrase 'one or more biomodifier groups attached to any positions'. In particular, it is unclear what specific biomodifier groups Applicant is claiming that are compatible with SEQ ID No. 1.

Claim 6: The claim as written is ambiguous because of the phrase 'a moiety which emit or cause to emit detectable radiation, a moiety which affect local electromagnetic fields, moieties which absorb or scatter radiation energy, heavy metals and compounds thereof and moieties which generate a detectable substance'. In particular, it is unclear what particular species Applicant is claiming that are compatible with the instant invention. Please clarify in order that one may ascertain what is being claimed.

103 REJECTIONS

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Srinivasan (US Patent No. 5,618,513).

Srinivasan discloses the radiolabeling of peptides using polyaminocarboxylate ligands (see entire document, especially, abstract). In particular, Srinivasan discloses that the peptide-chelate conjugates are labeled by reacting the conjugate with a select radionuclide. In addition, Srinivasan discloses that the reaction is performed by methods known in the art and preferably involve the use of a reducing agent such as stannous chloride (column 4, lines 26-32). Furthermore, Srinivasan discloses that a kit may be generated using the components (column 4, lines 42-54). Thus, both Applicant and the cited prior art disclose a kit comprising a peptide-chelate and a reducing agent.

PRIORTY DOCUMENT

10. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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SPECIFICATION

11. The disclosure is objected to because of the following informalities: the specification does not contain the heading 'Brief Description of the Drawing' and a description of the figure.

Appropriate correction is required.

COMMENTS/NOTES

12. It should be noted that no prior art has been cited against independent claim 1. However, Applicant MUST address and overcome the 112 rejections above. In particular, independent claim 1 is free of the art of record because of the requirements for X1 that are non-obvious modifications over the prior art.

13. Applicant is reminded that it has been held that the recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138). In particular, Applicant's attention is directed to claims 1 (lines 7, 17, and 18) and 9 (line 25).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

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Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
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September 24, 2009